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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222.123	12/29/1998	ROBERT A. RAY	6328-21	3601

7590 12/22/2003

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/222,123

Applicant(s)

RAY ET AL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-21, 24-27 and 29-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21, 24-27 and 29-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

This Office Action is in response to Applicant's Appeal Brief filed on September 25, 2003 and entered as Paper No. 27. Claims 19-21, 24-27 and 29-42 are pending. A new grounds of rejection is set forth below.

#### *Withdrawal of Rejections*

- All rejections in the previous Office Action are withdrawn in view of Applicants' arguments that there is no motivation for modifying the Bahl et al device to include a polyvinyl alcohol pad.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 19-21, 24-27 and 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over European publication 0022377 to Levine in view of US Patent 4,521,520 to Jacke.

Levine discloses a device for obtaining a biological sample to be analyzed. The device comprises a handle end (4) and a collection end (8). On the collection end of the device, the reference teaches that there is an opening (6), which may serve to facilitate removing a portion of the absorbent pad containing the sample. Also, there is an absorbent pad (10) on the collection end of the device. See figure 1. Levine discloses that the handle end of the device may be made from a polymeric material, such as polyethylene. The device may be folded to form a pouch in which the sample is stored.

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Levine differs from the instantly claimed invention in that it fails to teach polyvinyl alcohol as the absorbent material for the pad.

Jacke teaches devices and method for obtaining biological samples. The device of Jacke comprises a handle end having an absorbent pad attached to the collection end. The absorbent pad is polyvinyl alcohol (col. 3, lines 41-47). The polyvinyl alcohol collection pad contains several pores (70). With respect to the recited pore size, the ordinarily-skilled artisan would have been able to determine a suitable pore size according to the sample being collected and the analysis being performed. Jacke teaches that the pad may have reagents incorporated therein to assist in analyzing the sample. Jacke further teaches incorporate a receptacle with in kits where the collection will be performed at home.

It would have been obvious to one of ordinary skill in the art to use a polyvinyl alcohol pad in the device of Levine because of its ability to catch and hold a biological sample. Using a polyvinyl alcohol absorbent material reduces the chances of losing sample and increases the chances of obtaining a sample sufficiently large enough to perform analysis.

With respect to the presence of instructions in the kit, it would have been obvious to one of ordinary skill in the art to include instructions in the kit of Levine, especially where the kit is to be used at home, to make sure that the user operates the devices in the correct manner and collects the sample in the correct manner.

With respect to the claims reciting urine as the particular sample to be collected, the claims are not limited by such recitation because the patentability of claims directed to a device lies in structural components of the device and not materials the device is intended to work on.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (571) 272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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December 15, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700